

**REMARKS/ARGUMENTS**

Claims 5, 9, and 12-14 remain in this application. Claims 10, 30 and 33 have been cancelled.

**Rejection Under 35 U.S.C. §101**

The Examiner rejected claims 5, 9-10, 12-14, 30 and 33 under 35 U.S.C. §101 as lacking an apparent or disclosed patentable utility. The Examiner argues that sequence similarity to known proteins does not constitute “a real world” use for the claimed proteins. Specifically, the Examiner states:

It is clear from the instant specification that the nucleic acid encoding the NOV13 polypeptide has been assigned a function because of its similarity to known proteins....until some actual and specific significance can be attributed to the protein identified in the specification as NOV13, the instant invention is incomplete... and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.”

Applicants respectfully traverse. The NOV13 protein was not assigned a function solely because of its similarity to known proteins, as the Examiner contends. Applicants characterized this protein by conducting expression studies involving normal and cancerous cell lines to determine whether NOV13 was differentially expressed in cancer cell lines when compared to normal. (*See* pgs. 308-315). The results of these studies show that NOV13 is differentially expressed (100-fold) in a prostate cancer cell line when compared to the normal. (*See* Table 74, p. 310). Thus, it is readily apparent from these results that the differential expression of NOV13 can be used to detect prostate cancer in a sample. (*See* p. 315, lines 17-22). The use of NOV13 to detect prostate cancer in a sample is a specific, substantial asserted utility that satisfies the utility requirements of 35 U.S.C. §101.

In view of the above, Applicants respectfully request withdrawal of this rejection.

**Rejection Under 35 U.S.C. §112, First Paragraph—Enablement Requirement**

The Examiner rejected claims 5, 9-10, 12-14, 30 and 33 under 35 U.S.C. §112, first paragraph as non-enabled because the claimed invention is not supported by either a specific for substantial utility.

Applicants respectfully traverse. As explained above, the specification discloses and describes the use of NOV13 to detect prostate cancer in a sample. This use is specific and substantial and thus satisfies the requirements of 35 U.S.C. §112, first paragraph.

The Examiner further rejected claims 9-10, 12, 14, 30 and 33 under 35 U.S.C. §112, first paragraph. The Examiner states:

“Even if, *arguendo*, a patentable utility is found for the nucleic acid encoding SEQ ID NO: 28, claims 9-10, 12-14, 30 and 33 are rejected under 35 U.S.C. §112, first paragraph, because the specification, which would be enabling for a nucleic acid encoding a full-length NOV13 polypeptide of SEQ ID NO:28, does not reasonably provide enablement for a naturally occurring allelic variant...”

Applicants respectfully traverse. Claim 9 and dependent claims 12-14 do not relate to an allelic variant of NOV13. Claim 9 recites: The nucleic acid molecule of claim 5, wherein said nucleic acid molecule comprises a nucleotide sequence of SEQ ID NO: 27. Thus, since claim 9 does not relate to allelic variants, but to the nucleic acid encoding the full-length NOV13 polypeptide, this claim is clearly enabled. In fact, the Examiner recognized the enablement of this claim when he stated that the specification “would be enabling for a nucleic acid encoding a full-length NOV13 polypeptide.” (Office Action, p. 6).

With respect to Claims 10, 30 and 33, Applicants do not agree with the Examiner’s rejection, but in the interest of furthering prosecution, Applicants have cancelled these claims.

The Examiner further rejected claims 30 and 33 as not enabled because “the breadth of the claims is excessive since the claims read on all pharmaceutical compositions to treat all diseases.” (Office Action, p. 9).

As stated above, claims 30 and 33 have been cancelled in the interest of furthering prosecution, thus obviating this ground of rejection.

In view of the above, Applicants respectfully request withdrawal of this rejection.

**Rejection Under 35 U.S.C. §112, First Paragraph—Written Description**

The Examiner rejected claims 9-10, 12-14, 30 and 33 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states:

“The claims are drawn to naturally-occurring allelic variants of a nucleic acid encoding SEQ ID NO: 28, or nucleic acids encoding a naturally-occurring allelic variant of a polypeptide of SEQ ID NO: 28, or nucleic acids which hybridize to a nucleic acid encoding SEQ ID NO:28, or nucleic acids which comprises a sequence that differs at no more than 20% of the nucleotides in the coding sequence. These are genus claims...the specification and claim do not indicate what distinguishing attributes are shared by the members of this genus.” (Office Action pp. 9-10)

Applicants once again direct the Examiner’s attention to claim 9, which relates to a nucleic acid molecule comprising SEQ ID NO: 28. This claim, as well as dependent claims 12-14, do not relate to allelic variants as the Examiner contends. The written description for these claims is set forth in the specification on pages 92-97 and Tables 13A and 13B.

With respect to Claims 10, 30 and 33, Applicants do not agree with the Examiner’s rejection, but in the interest of furthering prosecution, Applicants have cancelled these claims.

In view of the above, Applicants respectfully request withdrawal of this rejection.

**Rejection Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 12-14 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner states:

“Claim 12 recites the term “stringent conditions,” which is a conditional term and renders the claim indefinite.” (Office Action, p. 11).

Applicants respectfully traverse. The term “stringent conditions” does not appear in claim 12 or dependent claims 13 and 14. Claim 12 recites: “A vector comprising the nucleic acid molecule of claim 9.”

Accordingly, in view of the above, Applicants respectfully request withdrawal of this rejection.

**Rejection Under 35 U.S.C. §102**

The Examiner rejected claims 10, 12-14 under 35 U.S.C. §102(b) as being anticipated by Ritter et al. Specifically, the Examiner states:

“The claims are drawn to nucleic acids which hybridize to SEQ ID NO: 27, vectors comprising these nucleic acids, and host cells comprising the vector. The Ritter et al reference teaches...UDP-glucuronosyltransferase...the nucleic acid encoding the UDP-glucuronosyltransferase is 60.6% identical to the nucleic acid of SEQ ID NO: 27 and would hybridize under stringent conditions to the nucleic acid.”

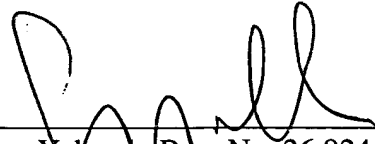
With respect to claim 10, although Applicants do not agree with the Examiner’s rejection, in the interest of furthering prosecution, this claim has been cancelled. Applicants traverse the Examiner’s rejection as it relates to claims 12-14. Claims 12-14 are not dependent on claim 10 and thus are not drawn to vectors or host cells comprising a nucleic acid that hybridizes to SEQ ID NO: 27, as the Examiner contends. Rather, claims 12-14 are dependent on claim 9 which relates to a nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 27. Accordingly, since the Examiner’s rejection as it relates to the Ritter reference depends on claims relating to nucleic acid molecules that hybridize to SEQ ID NO: 27, and since claims 12-14 do not contain this limitation, the Examiner’s rejection is unfounded.

In view of the above, Applicants request withdrawal of this rejection and submit that the claims are in condition for allowance.

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Respectfully submitted,



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